

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE / United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/687,529	10/16/2003	Peter Abel	33637/US	33637/US 5228		
7590 09/25/2006			EXAM	EXAMINER		
David E. Bruhn			FERNANDEZ, SUSAN EMILY			
DORSEY & WI	HITNEY LLP perty Department	ART UNIT	PAPER NUMBER			
Suite 1500, 50 S	South Sixth Street	1651				
Minneapolis, MN 55402-1498			DATE MAILED: 09/25/2006			

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	Application No. Applicant(		(s)			
Office Action Summary		10/687,52	9 .	ABEL ET AL.				
		Examiner		Art Unit				
		Susan E. I		1651				
Period fo	The MAILING DATE of this communication approximation ap	opears on the	cover sheet with the c	orrespondence ad	ddress			
WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR REP CHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CFR 1 SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory perior re to reply within the set or extended period for reply will, by statutely received by the Office later than three months after the mailed patent term adjustment. See 37 CFR 1.704(b).	DATE OF TH 1.136(a). In no even d will apply and wi ute, cause the appl	IIS COMMUNICATION ent, however, may a reply be tim II expire SIX (6) MONTHS from ication to become ABANDONEI	I. lely filed the mailing date of this of (35 U.S.C. § 133).				
Status		,						
1)	Responsive to communication(s) filed on <u>08</u>	Mav 2006.						
·	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.							
3)	, <del></del>							
,	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims							
4)⊠	4)⊠ Claim(s) <u>16-20,24,25,27-30 and 32-40</u> is/are pending in the application.							
•	4a) Of the above claim(s) is/are withdrawn from consideration.							
	Claim(s) is/are allowed.							
·	∑ Claim(s) <u>16-20,24,25,27-30 and 32-40</u> is/are rejected.							
7)								
8)□	Claim(s) are subject to restriction and	or election re	equirement.					
Applicati	on Papers							
9) ☐ The specification is objected to by the Examiner.								
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).								
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority ι	ınder 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
2) Notice 3) Information	t(s) se of References Cited (PTO-892) se of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/0 or No(s)/Mail Date	8)	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate	O-152)			

## **DETAILED ACTION**

The amendment filed May 8, 2006, has been received and entered.

Claims 1-15, 21-23, 26, and 31 are canceled. Claims 38-40 are new.

Claims 16-20, 24, 25, 27-30, and 32-40 are pending and examined on the merits.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-20, 24, 25, 27-30, 32-38, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the recitation "or channel" recited at line 4 of claim 16 and in claim 40, is considered new matter since the disclosure does not expressly specify that the analyte-impermeable, oxygen-permeable membrane does not have any channel. Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1651

Claims 16-20, 24, 25, 27-30, and 32-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Page 3

Claims 16 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the electrodes (see 5 of Figure 1) and the near-surface part of the diffusion channel for the analyte (see 4 of Figure 1). Thus, claims 16-20, 24, 25, 27-30, and 32-40 are rejected under 35 U.S.C. 112, second paragraph.

Claim 33 is indefinite since it is not clear what feature of the cross-section of the diffusion channel is used in the ratio. Specifically, it is not clear whether a parameter such as the area, circumference, diameter, or radius of the cross-section is used in the ratio that is determined. Therefore, the rejection of claim 33 under 35 U.S.C. 112, second paragraph is maintained.

Claim 35 is rendered indefinite by the phrase "outer concentration gradients." First, it is not clear which substance's concentration is included in the "outer concentration gradients".

Additionally, it is unclear what is defined by "outer", which is included in the phrases "outer concentration gradients" and "outer deposits". Is it referring to the region outside the channel entrances? Finally, "diffusion flow" renders claim 35 indefinite because it is not clear which "diffusion flow" is encompassed – that is, is unclear that the diffusion flow corresponds to the diffusion of the analyte. Thus, the rejection of claim 35 under 35 U.S.C. 112, second paragraph is maintained.

Art Unit: 1651

No claims are allowed. Claim 39 would be allowable if rewritten or amended to

overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444.

The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan E. Fernandez Assistant Examiner

Art Unit 1651

eon B. Lankford, Jr.

Rrintary Examiner

Art Unit 1651

sef